K071793

BARTON™
MEDICAL CORPORATION
www.bartonmedical.com

AUG - 3 2007

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510(k) Summary

Submitter Information:

Barton Medical Corporation
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Contact Person:

Lawrence W. Swol
Chief Quality Officer
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July 19, 2007

Manufacture:

Takano Co., Ltd.
137 Miyada-Mura, Kamiina-Gun
Nagano 399-4301 Japan

Device Information:

Trade/Proprietary Name:	I-1000
Common/Usual Name:	Convertible® I-Series Positioning and Transfer Chair
Classification Name:	Chair, Electric, Positioning

Legally Marketed Predicate Device:

Altimate Medical EasyStand Evolv; K062402, Sept. 21, 2006
Invacare Model LC Series Lift-Out Chair, K002171, Aug. 10, 2000

Device Description:

The Convertible® Positioning and Transfer Chair construction is made of steel tubular components, on to which is fitted foam filled upholstery. The mechanism allows the Convertible® Positioning and Transfer Chair to transform from the horizontal supine position into a chair, which can then be tilted. This is accomplished through the

hand-held controller, which in turn operates two DC linear actuators. The first DC actuator allows the Chair and patient profile to change from a sitting position to a horizontal or supine position suitable for transferring. The second DC linear actuator allows the I-1000 to be independently inclined to the rear (Tilt-in-Space). A hand-held push button controller is used to engage actuator motion and vary the I-1000's position. The electric system is composed of a 24-volt rechargeable battery, an external battery charger, and a control unit. Recharging of the battery is accomplished via the external battery charger.

The Convertible® Positioning & Transfer Chair is ideal for moving those patients who are unable to move themselves. The Convertible® Positioning and Transfer Chair have been specifically designed to provide a means of transferring a patient horizontally from a height adjustable bed or trolley, to the chair and vice versa. The patient will always be supported either on the bed and/or the chair and is never suspended. To achieve this, The Barton® Positioning and Transfer System (PTS®) must be used.

Intended Use:

The Convertible® I-1000 Positioning & Transfer Chair is an electric positioning chair with motorized positioning control that can be adjusted to various positions. The device is used to alter postural positions and to provide a means of transferring a patient horizontally from a height adjustable bed or trolley, to the chair and vice versa. The chair can then be transformed from a supine position into the sitting position without ever lifting the patient. This device may be used on a wide range of patients, including adults and children up to 1000 pounds.

Substantial Equivalence:

The Convertible® I-1000 Positioning and Transfer Chair and the predicate devices have similar, and in many cases, the same:

- Intended use,
- Basic construction,
- Principals of operation,
- Electrical and mechanical characteristics, and
- General safety and EMC compliance.

Performance Standards

Although no performance standards or special controls have been developed under Section 514 of the FDC Act for electric positioning chairs, Barton Medical Corporation has chosen to test the Convertible® I-1000 Positioning and Transfer Chair against self imposed load and repeatability test requirements. Representative sample for the device underwent load and repeatability testing to verify functional and performance characteristics.

Biocompatibility

Materials that may contact patients used on the Convertible® I-1000 Positioning and Transfer Chair are biocompatible. The material was evaluated for primary skin irritation in accordance with in the guidelines of the requirements of ISO 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization. Under the conditions of the study, no erythema and no edema were observed. The response of the test article was categorized as negligible.

Electromagnetic Compatibility and Electrical Safety

The Convertible® I-1000 I-Series Positioning and Transfer Chair meet the applicable requirements of IEC 60601-1 General Safety and IEC 60601-1-2 EMC.

Cited Standards

The Convertible® I-1000 Positioning and Transfer Chair conform to relevant portions of applicable guidance and standards that include the following:

- IEC 60601-1:1998 General Requirements for Safety
- IEC 60601-1-2:2001 Medical Electrical Equipment, Electromagnetic Compatibility
- JIS T9201:1998 Manually Propelled Wheelchairs
- ISO 10993-10:2003 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization
- EN 12531-12:1999 Castors and wheels. Hospital bed castors. Test condition 12: Test of castors for hospital beds
- JIS Z0237:2000 Adhesive Strength Measurement Conditions

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Barton Medical Corporation
% Intertek Testing Services NA, Inc.
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087
ATTN: Daniel W. Lehtonen

AUG - 3 2007

Re: K071793
Trade/Device Name: Convertible® I-Series (I-1000) Positioning and Transfer Chair
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric Positioning Chair
Regulatory Class: Class II
Product Code: INO, FMR
Dated: July 24, 2007
Received: July 25, 2007

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071793

Device Name:

Convertible® I-Series Positioning and Transfer Chair, Model I-1000

Indications for Use:

The Convertible® I-1000 I-Series Positioning and Transfer Chair is an electric positioning chair with motorized positioning control that can be adjusted to various positions. The device is used to alter postural positions and to provide a means of transferring a patient horizontally from a height adjustable bed or trolley, to the chair and vice versa. The chair can then be transformed from a supine position into the sitting position without ever lifting the patient.

This device may be used on a wide range of patients, including adults and children up to 1000 pounds.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K071793